

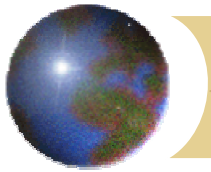
Application Assembly

Mary Kirker

Chief, Grants Management Officer

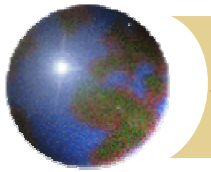
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December 13, 2004



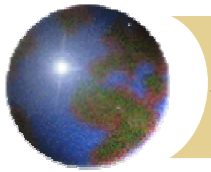
Application Assembly

- Overview of RFA
- New 398
- Examples of RFA specific forms and formats



Application

- ✦ Approximately \$150 Million Available
- ✦ Fund 3-6 networks --\$10-\$20 Million per network
- ✦ 7 Yr Project Period
- ✦ Foreign Institutions are not eligible to apply for this Network Leadership RFA
- ✦ Organizations can affiliate with more than 1 network



Network Application(s)

- ❁ Network Leadership must include support for:
 - ❁ Coordinating and Operations Center (CORE)
 - ❁ Statistical and Data Management Center (SDMC)
 - ❁ Network Laboratory Structure (NL)
- ❁ Can submit as one application combining all three components, as 1 component independent application(s) or some combination of two components.
- ❁ No clinical trial unit/site should be part of this application, unit/sites will be a separate RFA

- PHS 398 Face Page which includes the information for all components *in the application*

- PHS Form Page 2 & Page 2 Continued for all components in the application including all participating institutions and key personnel

[illegible]

Application Assembly All Applications

- Table of Contents –
 - if only one component use 398 Form Page 3
 - If two or more components are submitted use a modified version that includes a breakdown by component See Web site for format

Principal Investigator/Program Director (Last, First, Middle)
The name of the principal investigator/program director must be provided at the top of each printed page and each continuation page.

**RESEARCH GRANT
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Check if Appendix is included ☐

PHS 398 (Rev. 10/01) Form Page 3

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Check if Appendix is included ☐

PHS 398 (Rev. 10/01) Form Page 3

Table of Contents for Leadership Applications

Table of contents outlines the elements that may need to be included in an application. Sections with the prefix of (optional) indicate that the section is optional. Sections with the prefix of (required) indicate that the section is required. Sections with the prefix of (if applicable) indicate that the section is optional and should be included if it is applicable to the application.

ITEM	PAGE
1. Summary Sheet (do not use PHS 398 Form Page 3)	
2. PHS 398 Form Page 2	
3. Leadership Table 3	
4. Detailed Budget for Initial Budget Period	
5. Budget for Entire Proposed Period of Support	
6. Network Overview (20 pages or less)	
7. Organization	
8. Key Personnel	
9. Collaboration	
10. Special Features	

- PHS Form Page 4 (Budget for Initial Budget Period and Page 5 (Budget for Entire Project Period) composite budgets for all components in the application

Please do not scroll down to view the full specification. Make sure "Link oversized reports as image" is NOT checked in Print window

[illegible]

Application Assembly

All Applications

- **Overview of the Network Leadership**

- Summary page – do not use 398 Face Page see DAIDS Web site for format

- Title of the Network
- Period of Performance
- Network PI with Title and organizational affiliation
- Network Laboratories (NL) PI with title and organizational affiliation
- SDMC PI with title and organizational affiliation

SUMMARY SHEET			
1. TITLE OF NETWORK			
2. DATES OF PROPOSED PERIOD OF SUPPORT (month, day, year—MM/DD/YY)			
From		Through	
3. COMPONENTS SUBMITTED (1, 2, or 3 applications, in which combination): Indicate by checking the appropriate box below the combination of applications which comprise this Network Leadership.			
KEY CORE = Coordinating and Research Operations Center NL = Network Laboratory Structure SDMC = Statistical and Data Management Center			
One (1) U01 APPLICATION: (CORE+SDMC+NL) <input type="checkbox"/>			
Two (2) U01 APPLICATIONS: (CORE+SDMC) (NL) <input type="checkbox"/>			
or			
(CORE) (SDMC+NL) <input type="checkbox"/>			
or			
(CORE+NL) (SDMC) <input type="checkbox"/>			
Three (3) U01 APPLICATIONS: (CORE) (SDMC) (NL) <input type="checkbox"/>			
4. PRINCIPAL INVESTIGATOR FOR COORDINATING AND RESEARCH OPERATIONS CENTER (NETWORK PI)			
4a. NAME (Last, First, Middle)			
4b. TITLE			
4c. ORGANIZATION AFFILIATION			
4d. CONTACT INFORMATION			
EMAIL	TEL	FAX	
5. PRINCIPAL INVESTIGATOR FOR NETWORK LABORATORY			
5a. NAME			
5b. TITLE			
5c. ORGANIZATION AFFILIATION			
5d. CONTACT INFORMATION			
EMAIL	TEL	FAX	
6. PRINCIPAL INVESTIGATOR FOR STATISTICAL DATA AND MANAGEMENT CENTER			
6a. NAME			
6b. TITLE			
6c. ORGANIZATION AFFILIATION			
6d. CONTACT INFORMATION			
EMAIL	TEL	FAX	

- Overview of the Network Leadership

- Detailed Budgets, Page 4 & 5, for the entire Network Leadership package

[illegible]

Application Assembly

Coordinating and Operations Center (CORE)

– 398 Face Page

- Network Leader is the PI of the Core Application – must devote 50% effort

(Actual Size)		FORM 3-62	
Number of high school seniors _____		DATE _____ YEAR _____	
Grant Application Name _____ Address _____ City/State/Zip _____		Phone _____ County _____ County/State/Zip _____	
YES or NO Do you have a previous record for possession of weapons or controlled substances? _____			
YES or NO Do you have a previous record for possession of a firearm? _____			
1. PRESENTLY EMPLOYED OR STUDENT? Yes _____ No _____		2. EMPLOYMENT _____	
3. PRESENTLY ATTENDING COLLEGE OR UNIVERSITY? Yes _____ No _____		4. EMPLOYMENT _____	
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99. PRESENTLY ATTENDING COLLEGE OR UNIVERSITY? Yes _____ No _____		100. EMPLOYMENT _____	

– 398 Form Page 2 and Page 2 Continued

[illegible]

– Resources for the Core

– 398 Budget Page 4 and 5(s) including the following categories

- If proposing more than 1 of the 6 research areas, the **budget justification** must include the percentage breakdown by priority area

[illegible]

Application Assembly

Coordinating and Operations Center (CORE)

- Research Plan- 150 pages –
- Topics should be discussed in the following order:
 - Research Plan for High Priority Area(s)
 - If Applicable, Additional Requirement for NIDCR Research Priorities (up to 10 additional pages)

Application Assembly

Coordinating and Operations Center (CORE)

– Research Plan Format Continued

- PI, Network Leadership, Network Structure
- Core Operations Center
- Community Advisory Board(s)
- Proposed Clinical Trial Units & Units for HIV/AIDS
Clinical Trial Networks

Application Assembly

Coordinating and Operations Center (CORE)

- Proposed Clinical Trial Units & Units for HIV/AIDS Clinical Trial Networks
 - Must be able to recruit within 6 months of the award**
 - Each site must have 'on study' at least 20 participants per month – per site and network**
 - DO NOT REQUEST SUPPORT FOR CTUs OR SITES OPERATIONAL SUPPORT**
 - Suggested format on the DAIDS Web**

LEADERSHIP FOR HIV/AIDS CLINICAL TRIALS NETWORKS

Table 3: POTENTIAL CLINICAL TRIALS UNIT (CTU) AND RESEARCH SITES

1. Criteria used to select CTUs and Research Sites:
 (EXAMPLE: A= past performance in top 50% of current funded units, B= past performance in top 75% of current funded units, C= access to minority/ethnic populations etc.)

2. a. CTU Name:					
b. Administrative Component	d. CTU PI	f. Institution City and state (U.S.) or Country (non-U.S.)	h. Currently in a DAIDS Network?		k. Selection Criteria
			<input type="checkbox"/> Yes <input type="checkbox"/> No		
c. Clinical Research Site Name	e. Site Leader	g. Institution City and state (U.S.) or Country (non-U.S.)	i. Currently in a DAIDS Network?	j. Estimated Annual Enrollment	l. Selection Criteria
			<input type="checkbox"/> Yes <input type="checkbox"/> No		
			<input type="checkbox"/> Yes <input type="checkbox"/> No		
			<input type="checkbox"/> Yes <input type="checkbox"/> No		

Application Assembly

Coordinating and Operations Center (CORE)

- Research Plan Format Continued
 - Protocol Implementation Funds
 - Transition of Clinical Research Activities & Components

- **Ongoing Clinical Trials**

- Protocol
- Status
- Timeline
- Costs

LEADERSHIP FOR HIV/AIDS CLINICAL TRIALS NETWORKS LEADERSHIP

Table 4: TRANSITION OF CLINICAL RESEARCH ACTIVITIES AND COMPONENTS

Instructions: Table 4 contains 3 sections. The intent is to summarize ongoing clinical trials (include other clinical research activity such as epidemiologic or observational studies), identify existing Network components that are not included in the current application, and identify clinical research materials (e.g. research documents such as case report forms, regulatory files, study data, biologic specimens, etc.) at these locations and plans for their appropriate disposition. Appropriate supporting documentation (e.g. budgets) should be included in the application. 'New' or 'restructured' Networks proposing infrastructure or building on the research plans of existing Networks should also complete this section.

Section A. 1. Identify ongoing clinical trials by protocol number and name (a commonly used short name is acceptable). Include all clinical trials (ongoing or planned) that may not be completed at the time of award. Add as many rows as necessary. 2. Indicate the current enrollment status (i.e. at the time this application is being submitted) using the codes: P= pending enrollment; O= open to enrollment; C=Closed to enrollment (study is fully accrued). 3. If status = P or O indicate the percentage of total enrollment that has been accrued to date (i.e. the date of submission of this application) and identify that date that full enrollment is anticipated. For ongoing studies with full enrollment, indicate 100% and the date at which enrollment was stopped. 4. Indicate the total number of clinical research sites that are or will be enrolling participants in this clinical trial. 5. Indicate the date at which it is anticipated that all participant follow-up will be completed. 6. Indicate the Leadership costs (CORE, NL, SDMC) to complete this study after the estimated award date for this application. 7. Indicate the clinical research site costs to complete this study after the estimated award date for this application. 8. Add the Network and Clinical Research costs for each protocol. 9. Indicate total Leadership costs for all ongoing clinical trials. 10. Indicate total clinical research site costs for all ongoing clinical trials. 11. Indicate costs for all ongoing clinical trials.

Ongoing Clinical Trials							
1. Protocol Number and Name	2. Status	3. Current Enrollment (%) and Enrollment Completion Date (est.)	4. Number of Participating Sites (current plus planned)	5. Follow-up Completion Date (est.)	6. Network Costs (CORE, NL, SDMC)	7. Clinical Research Site Costs	8. Total Protocol Costs
Total Ongoing Protocol Costs					9.	10.	11.

Application Assembly

Coordinating and Operations Center (CORE)

– Transition of Clinical Research Activities and Components:

- Phase-Out of Network Infrastructure

LEADERSHIP FOR HIV/AIDS CLINICAL TRIALS NETWORKS LEADERSHIP

Table 4: TRANSITION OF CLINICAL RESEARCH ACTIVITIES AND COMPONENTS

Section B. 1. Identify existing Network components not proposed in this application. List in the following order: Operations office (ops), Network or central laboratory facilities (C-AL), Statistical or Data Management Center (stat, dm) and clinical trial units and research unit. Clinical units should be identified using current network nomenclature (e.g. HIVTU, AACTU, etc.), using a separate row for each Main unit, subunit, etc. Add rows as necessary. 2. Identify the type of organizations using acronym identified above (Ops, Lab, DM, etc.). 3. Briefly describe activities that are likely to be ongoing at the time of leave request. For example, identify protocols listed in Section A. 4. List the anticipated date by which all ongoing work is likely to be completed. 5. Indicate "Yes" if essential clinical trials exist at this location. All materials should be identified in Section B. below.

Phase-Out Network Infrastructure				
1. Component Name	2. Type	3. Ongoing Activity	4. Anticipated Phase-out Completion Date	5. Transfer Clinical Trial Materials? (Yes or No)

11/10/2004 Page 2 of 3

- Transfer of Clinical Trial Material

LEADERSHIP FOR HIV/AIDS CLINICAL TRIALS NETWORKS LEADERSHIP

Table 4: TRANSITION OF CLINICAL RESEARCH ACTIVITIES AND COMPONENTS

Section C. 1. Following the same general order as in Section B, list locations identified for phase out in Section B that house essential clinical research materials. Add rows as necessary. 2. Indicate the type of materials present, using a separate row for different types of materials. Types of materials may include regulatory documents, case report forms, clinical trial files, clinical research data, administrative data, biological specimens, etc. 3. Identify the planned location for these materials. 4. Identify the estimate date for the transfer of the material to a new location.

Transfer of Clinical Trial Materials			
1. Location	2. Type of Material	3. New Location	4. Anticipated Transfer Date

Application Assembly

Coordinating and Operations Center (CORE)

- Research Plan Format Continued
 - Performance Evaluation
 - Cross-Network Collaborations

Application Assembly Network Laboratory (NL)

- Each component in the application should include its own:
 - 398 Face Page -- PI must devote 50% effort
 - 398 Form Page 2
 - Resources for the Network Laboratory

Project Investigator/Project Director (Last, First, Middle)			
DESCRIPTION: See instructions. Specify the application's broad, long-term objectives and specific aims, making reference to the health-related needs of the target population and the mission of the agency. Describe the approach to the research design and methods for achieving these goals. Describe the information and information you will use to achieve these goals.			
In addition, include the following information:			
1. How the project will be implemented.			
2. How the project will be evaluated.			
3. How the project will be disseminated.			
4. How the project will be sustained.			
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124. How the project will be sustained.			

- 398 Budget Page 4 and 5

- If proposing more than 1 of the 6 research areas the **budget justification** must include the percentage breakdown by priority area

OTHER EXPENSES (describe by category)	
CONSORTIUM/CONTRACTUAL COSTS	
SUBTOTAL DIRECT COSTS FOR INITIAL BUDGET PERIOD (Item 7a, Page Page)	
CONSORTIUM/CONTRACTUAL COSTS	
TOTAL DIRECT COSTS FOR INITIAL BUDGET PERIOD	
\$BIR1TR Only: FEE REQUESTED	
Page _____	Page _____

Post-Test (Nov. 2005)	Pass	Exam Pass
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- Network Laboratories
Research Plan – 60

- 398 Budget Page 4 and 5

- SDMC Research Plan – 60 pages

[illegible]

Application Assembly

All

- Biographical Sketches for all application components
- Checklist for applicant

Application Assembly

New 398 changes

- Use new 09/2004 application 398 forms
- NIH now **requires** the use of Arial-11 or Helvetica-11 point font
- **Face Page:**
 - Title—Form field length has been increased to 81 characters
 - eRA Commons User Name field has been added. This data item is currently optional
 - Human Subjects Research box has been modified to

Actual Size

FEDERAL BUREAU OF INVESTIGATION		UNITED STATES DEPARTMENT OF JUSTICE	
Section of Health and Human Services Public Health Service Grant Application <small>(Do not include information already furnished to the agency.)</small>		LEADS TO BE FOLLOWED UP ON THIS CASE Type <input type="checkbox"/> Priority <input type="checkbox"/> Routine Review Group <input type="checkbox"/> Pending Collection Status <input type="checkbox"/> Not Included	
1. TITLE OF PROJECT (Do not exceed 10 characters, including spaces and punctuation)			
2. RESPONSE TO REQUEST FOR PROPOSALS OR FOR INFORMATION AND DISCUSSION <input type="checkbox"/> NO <input type="checkbox"/> YES Number _____ Title _____		3. INFORMATION ON PROGRAM DIRECTOR Do you know the name of the director? <input type="checkbox"/> Yes <input type="checkbox"/> No If yes, name the director: _____	
4. PROJECT TITLE:		5. MAILING ADDRESS (Include zip code)	
6. DEPARTMENT, SERVICE, LABORATORY, OR DIVISION		7. MAILING ADDRESS (Include zip code)	
8. REASON FOR SUBMISSION		9. MAILING ADDRESS (Include zip code)	
10. TELEPHONE AND FAX (Show state number and extension) TEL: _____ FAX: _____		11. MAILING ADDRESS (Include zip code)	
12. TRAINING, EDUCATION, AND RESEARCH No <input type="checkbox"/> Yes <input type="checkbox"/>		13. MAILING ADDRESS (Include zip code)	
14. TRAINING, EDUCATION, AND RESEARCH No <input type="checkbox"/> Yes <input type="checkbox"/>		15. MAILING ADDRESS (Include zip code)	
16. TRAINING, EDUCATION, AND RESEARCH No <input type="checkbox"/> Yes <input type="checkbox"/>		17. MAILING ADDRESS (Include zip code)	
18. TRAINING, EDUCATION, AND RESEARCH No <input type="checkbox"/> Yes <input type="checkbox"/>		19. MAILING ADDRESS (Include zip code)	
20. TRAINING, EDUCATION, AND RESEARCH No <input type="checkbox"/> Yes <input type="checkbox"/>		21. MAILING ADDRESS (Include zip code)	
22. TRAINING, EDUCATION, AND RESEARCH No <input type="checkbox"/> Yes <input type="checkbox"/>		23. MAILING ADDRESS (Include zip code)	
24. TRAINING, EDUCATION, AND RESEARCH No <input type="checkbox"/> Yes <input type="checkbox"/>		25. MAILING ADDRESS (Include zip code)	
26. TRAINING, EDUCATION, AND RESEARCH No <input type="checkbox"/> Yes <input type="checkbox"/>		27. MAILING ADDRESS (Include zip code)	
28. TRAINING, EDUCATION, AND RESEARCH No <input type="checkbox"/> Yes <input type="checkbox"/>		29. MAILING ADDRESS (Include zip code)	
30. TRAINING, EDUCATION, AND RESEARCH No <input type="checkbox"/> Yes <input type="checkbox"/>		31. MAILING ADDRESS (Include zip code)	
32. TRAINING, EDUCATION, AND RESEARCH No <input type="checkbox"/> Yes <input type="checkbox"/>		33. MAILING ADDRESS (Include zip code)	
34. TRAINING, EDUCATION, AND RESEARCH No <input type="checkbox"/> Yes <input type="checkbox"/>		35. MAILING ADDRESS (Include zip code)	
36. TRAINING, EDUCATION, AND RESEARCH No <input type="checkbox"/> Yes <input type="checkbox"/>		37. MAILING ADDRESS (Include zip code)	
38. TRAINING, EDUCATION, AND RESEARCH No <input type="checkbox"/> Yes <input type="checkbox"/>		39. MAILING ADDRESS (Include zip code)	
40. TRAINING, EDUCATION, AND RESEARCH No <input type="checkbox"/> Yes <input type="checkbox"/>		41. MAILING ADDRESS (Include zip code)	
42. TRAINING, EDUCATION, AND RESEARCH No <input type="checkbox"/> Yes <input type="checkbox"/>		43. MAILING ADDRESS (Include zip code)	
44. TRAINING, EDUCATION, AND RESEARCH No <input type="checkbox"/> Yes <input type="checkbox"/>		45. MAILING ADDRESS (Include zip code)	
46. TRAINING, EDUCATION, AND RESEARCH No <input type="checkbox"/> Yes <input type="checkbox"/>		47. MAILING ADDRESS (Include zip code)	
48. TRAINING, EDUCATION, AND RESEARCH No <input type="checkbox"/> Yes <input type="checkbox"/>		49. MAILING ADDRESS (Include zip code)	
50. TRAINING, EDUCATION, AND RESEARCH No <input type="checkbox"/> Yes <input type="checkbox"/>		51. MAILING ADDRESS (Include zip code)	
52. TRAINING, EDUCATION, AND RESEARCH No <input type="checkbox"/> Yes <input type="checkbox"/>		53. MAILING ADDRESS (Include zip code)	
54. TRAINING, EDUCATION, AND RESEARCH No <input type="checkbox"/> Yes <input type="checkbox"/>		55. MAILING ADDRESS (Include zip code)	
56. TRAINING, EDUCATION, AND RESEARCH No <input type="checkbox"/> Yes <input type="checkbox"/>		57. MAILING ADDRESS (Include zip code)	
58. TRAINING, EDUCATION, AND RESEARCH No <input type="checkbox"/> Yes <input type="checkbox"/>		59. MAILING ADDRESS (Include zip code)	
60. TRAINING, EDUCATION, AND RESEARCH No <input type="checkbox"/> Yes <input type="checkbox"/>		61. MAILING ADDRESS (Include zip code)	
62. TRAINING, EDUCATION, AND RESEARCH No <input type="checkbox"/> Yes <input type="checkbox"/>		63. MAILING ADDRESS (Include zip code)	
64. TRAINING, EDUCATION, AND RESEARCH No <input type="checkbox"/> Yes <input type="checkbox"/>		65. MAILING ADDRESS (Include zip code)	
66. TRAINING, EDUCATION, AND RESEARCH No <input type="checkbox"/> Yes <input type="checkbox"/>		67. MAILING ADDRESS (Include zip code)	
68. TRAINING, EDUCATION, AND RESEARCH No <input type="checkbox"/> Yes <input type="checkbox"/>		69. MAILING ADDRESS (Include zip code)	
70. TRAINING, EDUCATION, AND RESEARCH No <input type="checkbox"/> Yes <input type="checkbox"/>		71. MAILING ADDRESS (Include zip code)	
72. TRAINING, EDUCATION, AND RESEARCH No <input type="checkbox"/> Yes <input type="checkbox"/>		73. MAILING ADDRESS (Include zip code)	
74. TRAINING, EDUCATION, AND RESEARCH No <input type="checkbox"/> Yes <input type="checkbox"/>		75. MAILING ADDRESS (Include zip code)	
76. TRAINING, EDUCATION, AND RESEARCH No <input type="checkbox"/> Yes <input type="checkbox"/>		77. MAILING ADDRESS (Include zip code)	
78. TRAINING, EDUCATION, AND RESEARCH No <input type="checkbox"/> Yes <input type="checkbox"/>		79. MAILING ADDRESS (Include zip code)	
80. TRAINING, EDUCATION, AND RESEARCH No <input type="checkbox"/> Yes <input type="checkbox"/>		81. MAILING ADDRESS (Include zip code)	
82. TRAINING, EDUCATION, AND RESEARCH No <input type="checkbox"/> Yes <input type="checkbox"/>		83. MAILING ADDRESS (Include zip code)	
84. TRAINING, EDUCATION, AND RESEARCH No <input type="checkbox"/> Yes <input type="checkbox"/>		85. MAILING ADDRESS (Include zip code)	
86. TRAINING, EDUCATION, AND RESEARCH No <input type="checkbox"/> Yes <input type="checkbox"/>		87. MAILING ADDRESS (Include zip code)	
88. TRAINING, EDUCATION, AND RESEARCH No <input type="checkbox"/> Yes <input type="checkbox"/>		89. MAILING ADDRESS (Include zip code)	
90. TRAINING, EDUCATION, AND RESEARCH No <input type="checkbox"/> Yes <input type="checkbox"/>		91. MAILING ADDRESS (Include zip code)	
92. TRAINING, EDUCATION, AND RESEARCH No <input type="checkbox"/> Yes <input type="checkbox"/>		93. MAILING ADDRESS (Include zip code)	
94. TRAINING, EDUCATION, AND RESEARCH No <input type="checkbox"/> Yes <input type="checkbox"/>		95. MAILING ADDRESS (Include zip code)	
96. TRAINING, EDUCATION, AND RESEARCH No <input type="checkbox"/> Yes <input type="checkbox"/>		97. MAILING ADDRESS (Include zip code)	
98. TRAINING, EDUCATION, AND RESEARCH No <input type="checkbox"/> Yes <input type="checkbox"/>		99. MAILING ADDRESS (Include zip code)	
100. TRAINING, EDUCATION, AND RESEARCH No <input type="checkbox"/> Yes <input type="checkbox"/>		101. MAILING ADDRESS (Include zip code)	

Application Assembly

New 398 changes

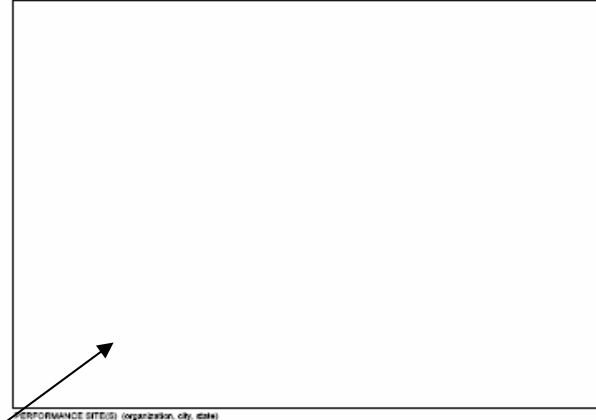
- **Form Page 2 & Form Page 2 Continued**

- 5 distinct sections—Description, Performance Sites, Key Personnel, Other Significant Contributors, and Stem Cells.

- Description/Abstract :
Instructions have been added requiring the PI to succinctly (2-3 sentences) describe the relevance of the proposed research to public health. Plain language is suggested

Principal Investigator/Program Director (Last, First, Middle):

DESCRIPTION: See instructions. State the application's broad, long-term objectives and specific aims, making reference to the health relatedness of the project (i.e., relevance to the mission of the agency). Describe concisely the research design and methods for achieving these goals. Describe the rationale and techniques you will use to pursue these goals. In addition, in two or three sentences, describe in plain, lay language the relevance of this research to public health. If the application is funded, this description, as it, will become public information. Therefore, do not include proprietary/confidential information. DO NOT EXCEED THIS SPACE PROVIDED.



PERFORMANCE SITE(S) (organization, city, state)

Application Assembly

New 398 changes

- Key Personnel Section : A field has been added for the eRA Commons User Name.

Provide the eRA Commons User Name for the Key Personnel

KEY PERSONNEL: List individuals. An individual's name is required to provide the required information to the eRA Commons. List all Key Personnel. List all other Key Personnel in alphabetical order. List last name first.			
Name	eRA Commons User Name	Organization	Review Project

- Other Significant Contributors: This is a new field that allows identification of individuals who will contribute to the scientific development or execution of the project but are *not* committing specified measurable effort.

OTHER SIGNIFICANT CONTRIBUTORS

Name	Organization	Review Project
------	--------------	----------------

Have an Embryonic Stem Cell? ☐ Yes ☐ No
If the proposed project involves human embryonic stem cells, list the name of the specific cell line(s) and the source of the cells. See http://www.fda.gov/oc/ohrt/embryonic_stem_cells.htm for more information.
If you do not have an embryonic stem cell, you must indicate that you have the cells within 30 days of the start of the project.

Other Key Personnel Information: ☒ Yes ☐ No. See http://www.fda.gov/oc/ohrt/embryonic_stem_cells.htm for more information. ☐ Yes ☐ No
Page 2 of 2

- Human Embryonic Stem Cells:

Application Assembly

New 398 changes

- **Budget Pages 4 & 5:**
Budget pages have been modified:

- Separate the Direct and F &A for Consortium
- New Subtotal for Direct Costs

TRAVEL							
PATIENT CARE COSTS		INPATIENT					
		OUTPATIENT					
ALTERATIONS AND RENOVATIONS		(Remize by category)					
OTHER EXPENSES		(Remize by category)					
CONSORTIUM/CONTRACTUAL COSTS		DIRECT COSTS					
SUBTOTAL DIRECT COSTS FOR INITIAL BUDGET PERIOD		(Rem 7a, Face Page)					
CONSORTIUM/CONTRACTUAL COSTS		FACILITIES AND ADMINISTRATIVE COSTS					
TOTAL DIRECT COSTS FOR INITIAL BUDGET PERIOD							
SBIR/STTR Only: FEE REQUESTED							

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CARE COSTS	OUTPATIENT						
ALTERATIONS AND RENOVATIONS							
OTHER EXPENSES							
CONSORTIUM/ CONTRACTUAL COSTS	DIRECT						
SUBTOTAL DIRECT COSTS		(Sum = Item 8a, Face Page)					
CONSORTIUM/ CONTRACTUAL COSTS	F&A						
TOTAL DIRECT COSTS							
TOTAL DIRECT COSTS FOR ENTIRE PROPOSED PROJECT PERIOD							
SBIR/STTR Only Fee Requested							
SBIR/STTR Only: Total Fee Requested for Entire Proposed Project Period		(Add Total Fee amount to "Total direct costs for entire proposed project period" above and Total F&A indirect costs from Checklist Form Page, and enter these as "Costs Requested for Proposed Period of Support on Face Page, Item 8b.)					
JUSTIFICATION: Follow the budget justification instructions exactly. Use continuation pages as needed.							

Application Assembly

New 398 changes

- **Biographical Sketch Format Page** : A field has been added for the eRA Commons User Name.
- **Personal Data Page**: Applicants are now requested to provide only the last four digits of the Social Security Number. Still voluntary.
- **Checklist Form Page**:
 - Foreign Application: Two distinct options are now provided 1) Grants at Foreign Institutions or 2) Domestic Grants with Significant Foreign Involvement. This data area also includes a text entry section to list countries involved.

Should describe what is in the application and/or section, Core, SDMC and/or Laboratories

Form Approved Through 09/30/2007

OMB No. 0925-0001

Department of Health and Human Services
Public Health Services

Grant Application

Do not exceed character length restrictions indicated.

LEAVE BLANK—FOR PHS USE ONLY.

Type	Activity	Number
Review Group	Formerly	
Council/Board (Month, Year)	Date Received	

1. TITLE OF PROJECT (Do not exceed 81 characters, including spaces and punctuation.)

Network A

2. RESPONSE TO SPECIFIC REQUEST FOR APPLICATIONS OR PROGRAM ANNOUNCEMENT OR SOLICITATION ☐ NO ☒ YES
(If "Yes," state number and title)

Number: RFA-AI-05-001 Title: Leadership for HIV/AIDS Clinical Trials Networks

3. PRINCIPAL INVESTIGATOR/PROGRAM DIRECTOR

New Investigator ☐ No ☐ Yes

3a. NAME (Last, first, middle)

3b. DEGREE(S)

3h. eRA Commons User Name

3c. POSITION TITLE

3d. MAILING ADDRESS (Street, city, state, zip code)

3e. DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT

3f. MAJOR SUBDIVISION

3g. TELEPHONE AND FAX (Area code, number and extension)

E-MAIL ADDRESS:

TEL:

FAX:

4. HUMAN SUBJECTS RESEARCH

4b. Human Subjects Assurance No.

5. VERTEBRATE ANIMALS ☐ No ☐ Yes

☐ No ☐ Yes

4c. Clinical Trial

☐ No ☐ Yes

4d. NIH-defined Phase III

Clinical Trial ☐ No ☐ Yes

4a. Research Exempt

☐ No ☐ Yes

If "Yes," Exemption No.

6. DATES OF PROPOSED PERIOD OF SUPPORT (month day year—MM/DD/YY)

7. COSTS REQUESTED BUDGET PERIOD

Cores are considered engaged in human subject research even when maintaining "operations centers" or "coordinating centers" for multi-site collaborative research.

SDMC can often be exempt

Labs are generally not exempt

7 Yr Project Period

Direct Costs: Direct Cost for both the main grantee and all subcontracts,

Excludes F &A for the grantee and subcontracts

Core Personnel Example

Personnel Continued							
NAME	ROLE ON PROJECT	TYPE APPT	EFFORT ON PROJECT	INST BASE SALARY	SALARY REQUESTED	FRINGE BENEFITS	TOTAL
Coordination and Logistic Support							
Cathy Cole	Internal Prog Coor	100	100	70000	70000	17500	87500
Tracy Cameron	Admin Affair Coor	100	100	65000	65000	16250	81250
Susan Stella	Admin Affair Coor	100	100	65000	65000	16250	81250
James Nictula	CSG	100	100	65000	50000	12500	62500
TBN	Contract Spec	100	100	65000	65000	16250	81250
Gerald Lewis	Technical Assis	100	100	40000	40000	10000	50000
Tom Clancey	Information Sup	100	100	40000	40000	10000	50000
Coordination and Logistic Support Subtotal:					395000	98750	493750
Protocol Development, Implementation and Oversight							
John Ripper	Deputy Clin Mgr	100	100	115000	115000	28750	143750
Jean Arthur	Section Mgr CTS	100	100	75000	75000	18750	93750
Jessica Lange	Section Mgr CTS	100	100	75000	75000	18750	93750
Anne Tyler	Sr Clin Trials Spec	100	100	65000	65000	16250	81250
Bridget Jones	Sr Clin Trials Spec	100	100	65000	65000	16250	81250
Homer Simpson	Sr Clin Trials Spec	100	100	65000	65000	16250	81250
Dorothy Parker	Sr Clin Trials Spec	100	100	65000	65000	16250	81250
Michael Swann	Clin Trial Spec	100	100	55000	55000	13750	68750
Nancy Boyd	Clin Trial Spec	100	100	55000	55000	13750	68750
Alan McGill	Clin Trial Spec	100	100	55000	55000	13750	68750
James Brown	Clin Trial Spec	100	100	55000	55000	13750	68750
Walter Cronkite	Clin Trial Spec	100	100	55000	55000	13750	68750
TBN	Clin Trial Spec	100	100	55000	55000	13750	68750
James Stewart	Associate CTS	100	100	45000	45000	11250	56250
John Lennon	Document Spec	100	100	5000	5000	1250	6250
Edward McBain	Clin Sec Admin	100	100	30000	30000	7500	37500
Thomas Jones	Clin Sec Admin	100	100	30000	30000	7500	37500
Protocol Development, Implementation & Oversight Subtotal					965000	241250	1206250
TOTAL CORE:					1,645,000	411250	2056250

Divide by Category

Principal Investigator/Program Director (Last, First, Middle):					Kirker, Mary C.		
DETAILED BUDGET FOR INITIAL BUDGET PERIOD					FROM	THROUGH	
DIRECT COSTS ONLY					3/1/2006	2/28/2007	
PERSONNEL (Applicant organization only)					DOLLAR AMOUNT REQUESTED (omit cents)		
NAME	ROLE ON PROJECT	TYPE APPT. (months)	% EFFORT ON PROJ	INST. BASE SALARY	SALARY REQUESTED	FRINGE BENEFITS	TOTAL
Mary C. Kirker	Principal Investigator	12	50.0	150,000	75,000	18,750	93,750
Administration							
Jane Doe	Proj. Manager	12	100.0	90,000	90,000	22,500	112,500
John Smith	Internal Prog Coor	12	100.0	70,000	70,000	17,500	87,500
Floyd Cross	Admin Assist	12	100.0	25,000	25,000	6,250	31,250
Carol Boon	Admin Assist	12	100.0	25,000	25,000	6,250	31,250
See Next Page							
SUBTOTALS					285,000	71,250	356,250

Provide Cumulative Total

CONSULTANT COSTS		
Coordination & Logistics: Susan Smith, Transcriber 500 hours @\$30 an hour		15,000
EQUIPMENT (itemize)		
Administration -- 1 LAN server -- \$5,000		
Protocol Development -- 2 LAN servers -- \$10,000		15,000
SUPPLIES (itemize by category)		
Administrative -- General Office Supplies -- 20,000, Computer software \$20,000		
Coordination & Logistics -- cassette tapes, notebooks, \$20,000		
Protocol Dev. -- General Office Supplies -- 20,000		
		80,000
TRAVEL		
Coordination and Logistics Travel of CAB, Exec Comm. Network meeting & Ad Hoc		55,000
PATIENT CARE COSTS	INPATIENT	
	OUTPATIENT	
ALTERATIONS AND RENOVATIONS (itemize by category)		
OTHER EXPENSES (itemize by category)		
Divided Equally between Administration, Coord & Log and Protocol Dev.		
Reproductions \$65,000		
Long Distance Secure lines and Faxes -- \$35,000		
Express Delivery -- \$35,000; Standard mail -- \$20,000		
		155,000
CONSORTIUM/CONTRACTUAL COSTS	DIRECT COSTS	
SUBTOTAL DIRECT COSTS FOR INITIAL BUDGET PERIOD (Item 7a, Face Page)		\$ 2,376,250
CONSORTIUM/CONTRACTUAL COSTS	FACILITIES AND ADMINISTRATIVE COSTS	
TOTAL DIRECT COSTS FOR INITIAL BUDGET PERIOD		\$ 2,376,250
SBIR/STTR Only: FEE REQUESTED		
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You may
provide details
on 398 form
page 4

If you have consortiums make sure you do a separate Page 4 and 5 for each consortium and add the totals on the overall budget of the component and/or the application

**BUDGET FOR ENTIRE PROPOSED PROJECT PERIOD
DIRECT COSTS ONLY**

BUDGET CATEGORY TOTALS		INITIAL BUDGET PERIOD (from Form Page 4)	ADDITIONAL YEARS OF SUPPORT REQUESTED			
			2nd	3rd	4th	5th
PERSONNEL: Salary and fringe benefits. Applicant organization only.		2,056,250	2,117,938	2,181,476	2,246,920	2,314,328
CONSULTANT COSTS		15,000	15,450	15,914	16,391	16,883
EQUIPMENT		15,000	20,000	20,000	10,000	10,000
SUPPLIES		80,000	82,400	84,872	87,418	90,041
TRAVEL		50,000	56,650	58,350	60,101	61,904
PATIENT CARE COSTS	INPATIENT					
	OUTPATIENT					
ALTERATIONS AND RENOVATIONS						
OTHER EXPENSES		155,000	159,650	164,440	169,373	174,454
CONSORTIUM/ CONTRACTUAL COSTS	DIRECT					
SUBTOTAL DIRECT COSTS (Sum = Item 8a, Face Page)		2,376,250	2,462,088	2,525,051	2,590,203	2,667,609
CONSORTIUM/ CONTRACTUAL COSTS	F&A					
TOTAL DIRECT COSTS		2,376,250	2,462,088	2,525,051	2,590,203	2,667,609
TOTAL DIRECT COSTS FOR ENTIRE PROPOSED PROJECT PERIOD						\$
SIR/STTR Only Fee Requested						
SIR/STTR Only: Total Fee Requested for Entire Proposed Project Period (Add Total Fee amount to "Total direct costs for entire proposed project period" above and Total F&A/indirect costs from Checklist Form Page, and enter these as "Costs Requested for Proposed Period of Support on Face Page, Item 8b.)						\$
JUSTIFICATION. Follow the budget justification instructions exactly. Use continuation pages as needed.						
ADMINISTRATIVE		COORDINATION AND LOGISTICS		PROTOCOL DEV		TOTAL
Personnel	\$356,250	\$493,750	\$1,206,250	\$2,056,250		
Consultant		\$15,000		\$15,000		
Equipment	\$5,000		\$10,000	\$15,000		
Supplies	\$40,000	\$20,000	\$20,000	\$80,000		
Travel		\$55,000		\$55,000		
Other Exp	\$51,666	\$51,667	\$51,667	\$155,000		
TOTALS	\$452,916	\$635,417	\$1,287,917	\$2,376,250		

Provide Breakdown by Support Areas

Each budget must include 2 page 5's if requesting more than 5 years

Principal Investigator/Program Director (Last, First, Middle): **Kirker, Mary C.**

**BUDGET FOR ENTIRE PROPOSED PROJECT PERIOD
DIRECT COSTS ONLY**

BUDGET CATEGORY TOTALS		06	07	ADDITIONAL YEARS OF SUPPORT REQUESTED		
				3rd	4th	5th
PERSONNEL: Salary and fringe benefits. Applicant organization only.		2,383,758	2,455,271			
CONSULTANT COSTS		17,389	17,911			
EQUIPMENT						
SUPPLIES		92,747	95,524			
TRAVEL		63,761	65,674			
PATIENT CARE COSTS	INPATIENT					
	OUTPATIENT					
ALTERATIONS AND RENOVATIONS						
OTHER EXPENSES		179,687	185,078			
CONSORTIUM/ CONTRACTUAL COSTS	DIRECT					
SUBTOTAL DIRECT COSTS (Sum = Item 8a, Face Page)						
CONSORTIUM/ CONTRACTUAL COSTS	F&A					
TOTAL DIRECT COSTS		2,737,338	2,819,458			
TOTAL DIRECT COSTS FOR ENTIRE PROPOSED PROJECT PERIOD						\$ 18,167,997
SIR/STTR Only Fee Requested						
SIR/STTR Only: Total Fee Requested for Entire Proposed Project Period (Add Total Fee amount to "Total direct costs for entire proposed project period" above and Total F&A/indirect costs from Checklist Form Page, and enter these as "Costs Requested for Proposed Period of Support on Face Page, Item 8b.)						\$
JUSTIFICATION. Follow the budget justification instructions exactly. Use continuation pages as needed.						
Percentage of High Priority Research Areas:						
Translational Research/Drug Development -- 60 %						
Optimization of Clinical Management, including Co-Morbidities -- 40 %						

More than 1 High Priority Areas – Provide % for Each Area

FORMAT FOR PROPOSED CLINICAL TRIAL UNITS

1. Criteria used to select CTUs and Research Sites:

(EXAMPLE: A= past performance in top 50% of current funded units, B= past performance in top 75% of current funded units, C= access to minority/ethnic population etc...)

A= Past Performance in top 50% of current funded units

B= Past Performance in Top 75% of current funded units

C= Access to new subject base

D= Access to minority/ethnic populations

2. a. CTU Name:

b. Administrative Component	d. CTU PI	f. Institution City and State (U.S.) or Country (non-U.S.)	h. Currently in a DAIDS Network?		k. Selection Criteria
AIDS Res All Bethesda	Mary Kirker	University of Maryland Bethesda, Maryland	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No		A
c. Clinical Research Site Name	e. Site Leader	g. Institution City and State (U.S.) or Country (non-U.S.)	i. Currently in a DAIDS Network?	j. Estimated Annual Enrollment	l. Selection Criteria
DC Mem. Physicians Grp	Jane Doe	District of Columbia	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	22	A
John Smith Fam. Med	John Smith	Rockville, Md	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	30	C
			<input type="checkbox"/> Yes <input type="checkbox"/> No		

Table 4: TRANSITION OF CLINICAL RESEARCH ACTIVITIES AND COMPONENTS

Instructions: Table 4 contains 3 sections. The intent is to summarize ongoing clinical trials (include other clinical research activity such as epidemiologic or observational studies). Identify existing Network components that are not included in the current application, and identify clinical research materials (e.g. research documents such as case report forms regulatory files, study data, biologic specimens, etc) at these locations and plans for their appropriate disposition. Appropriate supporting documentation (e.g. budgets) should be included in the application. "New" or "restructured" Networks proposing infrastructure or building on the research plans of existing Networks should also complete this section.

Section A. 1. Identify ongoing clinical trials by protocol number and name (a commonly used short name is acceptable). Include all clinical trials (ongoing or planned) that may not be completed at the time of award. Add as many rows as necessary. 2. Indicate the current enrollment status (i.e. at the time this application is being submitted) using the codes: P= pending enrollment; O= open to enrollment, C=Closed to enrollment (study is fully accrued). 3. If status = P or O indicate the percentage of total enrollment that has been accrued to date (i.e. the date of submission of this application) and identify that date that full enrollment is anticipated. For ongoing studies with full enrollment, indicate 100% and the date at which enrollment was stopped. 4. Indicate the total number of clinical research sites that are or will be enrolling participants in this clinical trial. 5. Indicate the date at which it is anticipated that all participant follow-up will be completed. 6. Indicate the Leadership costs (CORE, NL, SDMC) to complete this study after the estimated award date for this application. 7. Indicate the clinical research site costs to complete this study after the estimated award date for this application. 8. Add the Network and Clinical Research costs for each protocol. 9. Indicate total Leadership costs for all ongoing clinical trials. 10. Indicate total clinical research site costs for all ongoing clinical trials. 11. Indicate costs for all ongoing clinical trials.

Ongoing Clinical Trials

1. Protocol Number and Name	2. Status	3. Current Enrollment (%) and Enrollment Completion Date (est.)	4. Number of Participating Sites (current plus planned)	5. Follow-up Completion Date (est.)	6. Network Costs (CORE, NL, SDMC)	7. Clinical Research Site Costs	8. Total Protocol Costs
A5165	O	54%/8-06	17	9-07	\$385,000	\$1,456,000	\$1,841,000
Total Ongoing Protocol Costs					⁹ \$385,000	¹⁰ \$1,456,000	¹¹ \$1,841,000

Table 4: TRANSITION OF CLINICAL RESEARCH ACTIVITIES AND COMPONENTS

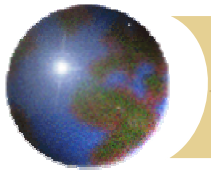
Section B. 1. Identify existing Network components not proposed in this application. List in the following order: Operations office (ops), Network or central laboratory facilities (Lab), Statistical or Data Management Centers (stats, dm) and clinical trial units and research site. Clinical units should be identified using current network terminology (e.g. HVTU, AACTU, etc.), using a separate row for each Main unit, subunit, etc. Add rows as necessary. 2. Identify the type of organization using acronyms identified above (Ops, Lab, DM, etc.). 3. Briefly describe activities that are likely to be ongoing at the time of new award. For example, identify protocols listed in Section A. 4. List the anticipated date by which all ongoing work is likely to be completed. 5. Indicate 'Yes' if essential clinical trials exist at this location. All materials should be identified in Section B. below.

Phase-Out Network Infrastructure				
1. Component Name	2. Type	3. Ongoing Activity	4. Anticipated Phase-out Completion Date	5. Transfer Clinical Trial Materials? (Yes or No)
University of XXXX	AACTU	Subject Follow-up	9/2007	Yes

Table 4: TRANSITION OF CLINICAL RESEARCH ACTIVITIES AND COMPONENTS

Section C. 1. Following the same general order as in Section B., list locations identified for phase out in Section B that house essential clinical research materials. Add rows as necessary. 2. Indicate the type of materials present, using a separate row for different types of materials. Types of materials may include regulatory documents, case report forms, clinical trial files, clinical research data, administrative data, biological specimens, etc. 3. Identify the planned location for these materials. 4. Identify the estimate date for the transfer of the material to a new location.

Transfer of Clinical Trial Materials			
1. Location	2. Type of Material	3. New Location	4. Anticipated Transfer Date
Univ. of XXXX	Regulatory Documents	Univ of YYYY	09/2007
Univ. of XXXX	Case Report Forms	Univ of YYYY	09/2007
Univ. of XXXX	Clin. Res. Data	Univ of YYYY	09/2007
Univ. of XXXX	Biological Specimens	Repository	09/2007



Questions?

- ✿ <http://grants1.nih.gov/grants/funding/phs398/phs398.html>
- ✿ <http://www.niaid.nih.gov/daids/rfa/network06/default.html>